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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVENUE, SUITE 5400
SEATTLE, WA 98104-7092

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/749,123	GRAVETT ET AL.	
	Examiner	Art Unit	
	Jagadishwar R. Samala	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *154-172 and 241-249* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *154-172 and 241-249* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *04/07/2005 & 06/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Applicant's election without traverse of group II, claims 154-172 and 241-249 in the reply filed on April 2, 2007 is acknowledged. Applicant's election of species is acknowledged. Claims 154-172 and 231-249 are pending and presented for examination. Claims 1-153 and 173-240 are cancelled.

Drawing

2. The drawing filed on December 30, 2003 has been acknowledged.

Information Disclosure Statement

3. The Information Disclosure Statement filed on April 07, 2005 and June 23, 2006 has been received and entered. The reference cited on the PTO-1449 Form have been considered by the examiner and a copy is attached to the instant Office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 154-157, 161,165, 166,168, 172, 241-246 are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US 2001/0055615 A1).

With respect to claims 154-157, 161,165, 166 and 168,Wallace discloses a method of tissue repair and tissue related applications comprising a

composition suitable for use in tissue engineering application such as, tissue sealants, in tissue augmentation, in tissue repair, as hemostatic agent, in preventing tissue adhesion, in the prevention of surgical adhesion, in providing surface modifications, and in drug delivery application (see para 0066). And also tissue treatment polymeric composition comprising biologically active substance such as antibiotics, antineoplastic agents, antiangiogenic agents, and the like, suited for use in a variety of biological tissue related applications when rapid adhesion to the tissue and gel formation is desired (see abstract). And further the tissue treatment composition can be used for reducing the formation of adhesions after a surgical procedure in a patient by applying onto the damaged tissue or organ either by spraying or by applying composition, to form a hydrogel on the tissue surface. The medical procedures include gynecological, abdominal, neurosurgical, cardiac, and orthopedic indications (see 0071). And further, composition can be applied as coatings to implants to affect the surface properties of implants or to help adhere implants to tissue surfaces e.g. catheters or breast implants to reduce or stop excessive fibrosis (see 0075).

With respect to claims 241-246, Wallace discloses tissue treatment composition comprising, synthetic polymer. Suitable synthetic hydrophilic polymer includes, polyalkylene oxide, such as polyethylene oxide and multifunctionally activated polyalkylene oxides, such as polyethylene glycol, (see 0039 and 0040). And also chain extenders or linking groups like alpha hydroxyl acids such as lactic acid and glycolic acid; poly(lactones) can be incorporated into one or both of the multifunctionally activated polymeric composition to

provide a site for enzymatic degradation (e.g. double-bond carbon and carbonyl carbon would be anticipated to have this effect, see 0047 and 0048).

6. Claims 154, 155, 161, 169-172, 241-246 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhee et al. (US 6,166,130).

With respect to claims 154 and 155, Rhee discloses a method for using the crosslinked polymer compositions to prevent the formation of surgical adhesions, as bioadhesives for tissue augmentation and also to coat a surface of a synthetic implant (see abstract). And also the crosslinked polymer composition comprise a synthetic polymer containing multiple nucleophilic and two or more electrophilic groups and/or biologically active agents such as growth factors may be delivered from the composition to a local tissue site in order to facilitate tissue healing and regeneration (The biological agents or active agents refers to organic molecules which exert biological effects in vivo, see column 15, line 34-40). And further, the crosslinked polymer composition can be used to coat tissues in order to prevent the formation of adhesions following surgery or injury to internal tissues or organs (e.g. the first and second synthetic polymers are mixed, then a thin layer of the reaction mixture is applied to the tissues comprising, surrounding, and/or adjacent to the surgical site before substantial crosslinking has occurred between the synthetic polymer).

With respect to claim 161, breast implants can be coated using the polymer composition in order to minimize capsular contracture (see column 20, line 45-47).

With respect to claims 169-172, Rhee discloses the method of using the crosslinked polymer compositions to block or fill various lumens and voids in the body of a mammalian subject. The crosslinked polymer compositions can also be coated onto the interior surface of a physiological lumen, such as a blood vessel or Fallopian tube, thereby serving as a sealant to prevent restenosis of the lumen following medical treatment, such as e.g. balloon catheterization to remove arterial plaque deposits from the interior surface of a blood vessel or removal of scar tissue or endometrial tissue from the interior of a Fallopian tube (see column 21, line 1-20).

With respect to claims 241-246, Rhee discloses multifunctionally activated synthetic polymers capable of reacting with one another i.e., nucleophilic groups reacting with electrophilic groups, to form covalent bonds. Preferred multifunctionally activated polyethylene glycols for the use in the composition includes polyethylene glycols containing succinimidyl groups (see column 9, line 23-26). The backbone of each polymer is preferably a polyalkylene oxide, particularly ethylene oxide, propylene oxide, and mixture thereof. Examples of difunctional alkylene oxides can be represented by: X-polymer-X and Y-polymer-Y. The required functional groups X or Y is commonly coupled to the polymer backbone by a linking group "Q" (wherein Q = $-O-(CH_2)_n-$). An additional group, represented as "D", can be inserted between the polymer and the linking group to increase degradation of the crosslinked polymer composition in vivo, for e.g. for use in drug delivery application. The biodegradable groups "D" includes lactide,

glycolide, poly(alpha-hydroxy acid) and various di- or tripeptides (see column 5, line 1-55).

7. Claims 154-157, 159 and 160 are rejected under 35 U.S.C. 102(b) as being anticipated by Wadstrom (5,631,011).

With respect to claims 154-157, Wadstrom discloses a tissue treatment composition comprising fibrin or fibrinogen and a biodegradable and biocompatible polymer capable of forming a viscous aqueous solution with biological tissue in vivo and capable of slow-release of a drug incorporated into it for local administration of therapeutic substance or for anti-adherence purposes, for wound healing etc (see abstract). And also, discloses the method of using the tissue treatment composition for preventing the adherence of adjacent tissues in surgical procedures such as ear, nose, and throat surgery, general surgery, dentistry, neurosurgery, plastic surgery, thorax and vascular surgery, abdominal surgery, orthopedics, accident surgery, gynecology, urology, and ophthalmology (see column 2, line 10-15). And also, the composition also markedly reduced the inflammatory reaction, which indicates that the wound healing is induced by regeneration of tissue rather than formation of scar tissue and shrinkage and completely abolished the development of adhesions (see column 11, line 20-35).

8. Claims 154, 155 and 158 are rejected under 35 U.S.C. 102(b) as being anticipated by Prior et al. (US 6,280,727 B1).

With respect to claim 158, Prior discloses a method of using a composition in the field of tissue treatment and repair. The composition comprises hydrophilic polymers such as polyalkylene oxides, preferably polyethylene glycol (see

column 10, line 21-23) and biological and/or therapeutic agents for delivery to the site of application or on the body of the subject. And also the compositions are useful in controlling diffuse bleeding from cancellous bone surfaces, which can pose problems during a variety of different surgical procedures, such as in the field of orthopedics, neurosurgery, plastic and reconstructive surgery, spinal surgery and oral-maxillo facial surgery. Further post-surgical application of the compositions can therefore be used to lessen post-surgical blood loss.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 154, 162-164, 167 and 247-249 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 2001/0055615 A1) or Rhee

et al. (US 6,166,130) or Wadstrom (5,631,011) in view Vacanti et al. (US 5,716,404) and

With respect to claims 154 and 162-164, Wallace, Rhee and Wadstrom discloses as above.

With respect to claim 162-164, Wallace, Rhee and Wadstrom differs from the instant claim by not explicitly reciting a method of using the composition to further prevent the adhesion formation of biological tissue after breast surgery.

With respect to claims 162-164, Vacanti discloses a method and compositions for reconstruction or augmentation of breast tissue. Dissociated cells, preferably muscle cells, are implanted in combination with a suitable biodegradable, polymeric matrix to form new tissue. Further compositions also includes bioactive molecules that enhance vascularization of the blood vessels into the forming tissue and/or the deposition and organization of fibrous tissue around the implant.

In view of the above teachings, it would have been obvious to one of ordinary skill in the art to modify the compositions disclosed by Wallace, Rhee and Wadstrom patent to include compositions for reconstruction or augmentation of breast tissue because Vacanti teaches that the incorporation of the a suitable biodegradable, polymeric matrix comprising bioactive molecules to from new tissue, preferably for reconstruction or augmentation of breast tissue.

Because the compositions for reconstruction or augmentation of breast tissue are effective to provide methods and materials to inhibit ingrowths of fibrotic breast structures which is tissue, not foreign material such as silicone,

and has the appearance of normal tissue, one of ordinary skill in the art would have been motivated to incorporate the compositions for reconstruction or augmentation of breast tissue in the composition advanced by Wallace, Rhee and Wadstrom. Based on the teaching of Vacanti, there is reasonable expectation that the polymeric matrix to form new breast tissue containing composition would be highly desirable for breast tissue augmentation. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate or make use of the composition for reconstruction or augmentation of breast tissue of the composition advanced by Wallace, Rhee and Wadstrom patents in view of the composition taught by Vacanti.

12. Claims 154, 167 and 247-249 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al. (US 2001/0055615 A1) or Rhee et al. (US 6,166,130) or Wadstrom (5,631,011) in view of Pasqualini et al. (US 5,922,676) and Hunter et al. (US 2002/0055666 A1).

With respect to claims 154 and 167 and 247-249, Wallace, Rhee and Wadstrom discloses as above.

With respect to claim 167, 247-249, Wallace, Rhee and Wadstrom differs from the instant claim by not explicitly reciting a method of using the composition to further prevent the adhesion formation of biological tissue after colon tumor resection surgery and composition comprising synthetic polymer and drug is cell-cycle inhibitor.

With respect to claim 167, Pasqualini discloses a method of inhibiting angiogenesis and treating pathologies with angioproliferative components. And also the methods provide for inhibition of the metastasis of osteosarcoma, melanoma, and epithelial tumor cells such as colon, breast or ovarian carcinoma (see abstract and column 2, line 443-46).

With respect to claims 247-249, Hunter discloses a methods, device and composition for treating a wide variety of hyper-proliferative diseases and conditions utilizing radiation and cell-cycle inhibitors. And also, devices may be formed of a carrier such as synthetic polymer and the cell-cycle inhibitor is a taxane (e.g. paclitaxel or derivatives thereof) is carried by the carrier material by being absorbed by or incorporated into or onto the carrier material prior to the body contact member being positioned against the site to be treated (see abstract and para 0019).

In view of above teachings, it would have been obvious to one of ordinary skill in the art to modify the compositions disclosed by Wallace, Rhee and Wadstrom patent to include compositions and method for preventing the adhesion formation after surgery to colon tumor and further tissue adhesion composition may be used for slow-release of a drug incorporated into it.

When these references are taken together, one would have been motivated to do so, with reasonable expectation of success because it is always desirable to have compositions as bioadhesives, for reducing post-surgical adhesion formation/reformation in mammals following surgical injury and for coating surfaces of synthetic implants, as drug delivery matrices and increase

industrial applicability. The techniques and skill required for making such a tissue treatment compositions is conventional knowledge or well within the skills of ordinary artisan as evidenced by cited reference.

As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine these references and make use of the composition for preventing the adhesion formation after surgery to colon tumor and further tissue adhesion composition may be used for slow-release of a drug like cell-cycle inhibitor of the composition advanced by Wallace, Rhee and Wadstrom patents in view of the composition taught by Pasqualini and Hunter.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jagadishwar R. Samala whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER